

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

SCIELE PHARMA, INC. and SCIELE)	
PHARMA CAYMAN LTD.,)	
)	
Plaintiffs,)	Civil Action No. 07-664 (GMS)
v.)	
)	ORAL ARGUMENT REQUESTED
MYLAN PHARMACEUTICALS, INC. and)	
MYLAN LABORATORIES, INC.,)	PUBLIC VERSION
)	
Defendants.)	

**MYLAN'S MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION
FOR LEAVE TO FILE A SUR-REPLY IN OPPOSITION TO MYLAN'S
RULE 12(b)(1) MOTION TO DISMISS FOR LACK OF STANDING**

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Mylan respectfully submits this memorandum in opposition to Sciele's motion for leave to file a sur-reply in opposition to Mylan's motion to dismiss for lack of standing and subject matter jurisdiction.

I. The Court Should Deny Sciele's Motion For Leave To File A Sur-Reply.

Nothing here warrants Sciele's submission of a sur-reply, which is not contemplated or otherwise permitted by local rule. *See* Delaware Local Rule 7.1.3. Nor, as Sciele suggests, has Mylan somehow violated the local rule governing reply briefs. (*See* Sciele Mot. at 1).¹

REDACTED

(*See* Mylan Reply at 2).² As Sciele concedes, Mylan did not even have the 2004 Agreement and the 2007 Amendment until Sciele's response, and so could not have addressed them any earlier than it did. Truth be told, however, it simply does not matter, because those agreements did not materially alter or diminish the substantial rights that Bayer holds in the patent, as fully set forth in Mylan's reply brief and below.

II. Under All Of The Agreements, Bayer Still Retains Substantial Rights In The Patent That Defeat Sciele's Standing.

Contrary to Sciele's assertion, Mylan has not ignored any "relevant facts" in the 2007 Amendment. (*See* Sciele Sur-Reply at 2).³ As Mylan pointed out in its reply brief, while

¹ All references to "Sciele Mot." are to Plaintiffs' Motion For Leave To File A Sur-Reply In Opposition To Defendants' Motion To Dismiss Plaintiffs' Complaint For Lack Of Standing And Subject Matter Jurisdiction.

² All references to "Mylan Reply" are to Reply Memorandum In Support Of Defendant Mylan's Rule 12(b)(1) Motion To Dismiss Plaintiff Sciele's Complaint For Lack Of Standing And Subject Matter Jurisdiction.

³ All references to "Sciele Sur-Reply" are to Plaintiffs' Sur-Reply In Opposition To Defendants' Motion To Dismiss Plaintiffs' Complaint For Lack Of Standing And Subject Matter Jurisdiction, which is Appendix A to Sciele's Motion.

REDACTED

See Vaupel Textilmaschinen v. Meccanica Euro Italia, 944 F.2d 870, 875 (Fed. Cir. 1991) (noting that the court should also “look at what rights have been retained by [the patentee].”).

REDACTED

(*See Mylan Reply* at 6-14). These rights and obligations are, to say the least, substantial, and more than enough to preclude standing. *See McNeilab, Inc. v. Scandipharm, Inc.*, 95 F.3d 1164, 1996 WL 431352, at *1-2 (Fed. Cir. July 31, 1996) (unpublished) (noting that there is no standing if the patentee retains “any substantial right under the patent”).

Sciele’s continued insistence that Section 16.3 of the 2004 Agreement—as opposed to Section 16.2—controls the right to sue in this case also misses the point. *ee* Sciele Sur-Reply at 2).

REDACTED

⁴ All references to “Marsden Decl.” are to the Declaration of William J. Marsden, Jr., Esq., submitted in connection with Sciele’s Opposition To Defendants’ Motion To Dismiss Plaintiffs’ Complaint For Lack Of Standing And Subject Matter Jurisdiction.

REDACTED

REDACTED

(See Mylan Reply at 14-15).

REDACTED

No

more is required to defeat Sciele's standing to sue.

III. Dismissal Is Especially Appropriate Here In Light Of The Hatch-Waxman Act And The Unwarranted 30-Month Stay That Sciele Has Secured By Prematurely Filing Suit Without Bayer.

Mylan has not, contrary to Sciele's assertion, misstated the law on standing. The general rule requires dismissal when the plaintiff lacks standing to sue in its own name without

the patentee. *See Textile Prods., Inc. v. Mead Corp.*, 134 F.3d 1481, 1485 (Fed. Cir. 1998) (affirming district court's dismissal of the plaintiff's patent infringement claims where the plaintiff was an exclusive licensee, but not an assignee, of the patent-in-suit); *Prima Tek II v. A-Roo Co.*, 222 F.3d 1372, 1382 (Fed. Cir. 2001) (dismissing an action brought by an exclusive licensee due to its failure to join the patent owner); *Procter & Gamble Co. v. Paragon Trade Brands, Inc.*, 917 F. Supp. 305, 307-11 (D. Del. 1995) (dismissing exclusive licensee's patent infringement counterclaim for lack of standing for failure to include actual patent owner); *Monsanto Co. v. Aventis Cropscience SA*, 226 F. Supp. 2d 531, 541 (D. Del. 2002) (partially dismissing action for lack of standing because licensees did not own "all substantial rights" in the patent). Indeed, as the Supreme Court explained, "the presence of the owner of a patent as a party is indispensable . . . to give jurisdiction under the patent laws" *Indep. Wireless Tel. Co. v. Radio Corp. of Am.*, 269 U.S. 459, 468 (1926).

Dismissal is especially appropriate here given the enormous prejudice that Mylan is already suffering, and will continue to suffer, if amendment or joinder of Bayer is allowed. Mylan is laboring under a 30-month stay of approval that would not have occurred had Sciele not filed suit prematurely without Bayer. None of the cases cited by Sciele—and nor is Mylan aware of any court that has—permitted joinder where, as here, the prejudice to the defendant was so extreme. (See Sciele Sur-Reply at 3). In *Mentor*, for example, the Federal Circuit ordered joinder only after assuring itself that joinder "will not prejudice the defendant." *Mentor H/S, Inc. v. Medical Device Alliance*, 244 F.3d 1365, 1373 (Fed. Cir. 2001). Neither *Intellectual Property Development* nor *Abbott* addressed the issue of prejudice at all—much less in the Hatch-Waxman context where a prematurely and improperly filed suit has such drastic consequences (*i.e.*, an automatic 30-month injunction on the approval of Mylan's competing generic drug

without the need for showing any of the factors necessary for such relief). *See Intellectual Prop. Dev., Inc. v. TCI Cablevision of Cal., Inc.*, 248 F.3d 1333 (Fed. Cir. 2001); *Abbott Labs. v. Diamedix Corp.*, 47 F.3d 1128 (Fed. Cir. 1995). This prejudice alone weighs decidedly in favor of dismissal, which will not leave Bayer or Sciele without a remedy.

Sciele's arguments regarding the Hatch-Waxman "compromise" and that dismissal is wrong because it would jeopardize the 30-month stay make no sense and turn the analysis on its head. If Sciele had no standing to sue alone as Mylan contends, then Sciele had no right to file this suit in the first instance, let alone to file just to get a 30-month stay. Bayer, moreover, admittedly and intentionally chose not to file suit against Mylan. By foregoing suit, Bayer blew the 45-day deadline for obtaining—and therefore is not entitled to—a 30-month stay either. Under Sciele's distorted logic, the Court should simply ignore all of this and effectively fix the problem by adding Bayer to a suit that Sciele should not have filed, and indeed lacked standing to file, in the first instance, and in doing so continue a 30-month stay that neither Bayer nor Sciele is entitled to. In a word, that is nonsense. If Sciele lacked standing and should not have filed in the first place, and therefore is not entitled to a 30-month stay, then it should not be able to fix the problem after-the-fact by adding a party (Bayer) that intentionally missed the 45-day deadline. The Hatch-Waxman compromise demands nothing different, and certainly does not require that this Court reward Sciele and Bayer with a stay to which neither is lawfully entitled.

CONCLUSION

The Court should deny Sciele's motion for leave to file a sur-reply, and dismiss this action for lack of standing and jurisdiction.

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